UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

UNITED STATES OF AMERICA,
ex rel. BECKY ROBERTS
and LORI PURCELL — CIVIL ACTION 3-2-2199

VERSUS — U.S. DISTRICT JUDGE ROBERT G. JAMES

AGING CARE HOME HEALTH, INC.
Et al

U.S. MAGISTRATE JUDGE JAMES D. KIRK

REPORT AND RECOMMENDATION

Before the court is the United States' Motion for Partial Summary Judgment, **Doc. #149**, referred to me by the district judge for report and recommendation.

This is a *qui tam*[1], or whistle blower action, filed by Relators Becky Roberts and Lori Purcell under the False Claims

[1] Black's Law Dictionary explains that a plaintiff in a qui tam action sues "as well" for the government as for himself. A qui tam action, or action by common informer, has been defined as a civil proceeding brought 'under a statute which imposes a penalty for the doing or not doing an act, and gives that penalty in part to whomsoever will sue for the same, and the other part to the commonwealth, or some charitable literary, or other institution, and make it recoverable by action.' Bouvier's Law Dictionary (3d ed). The action's appellation comes from the Latin phrase 'qui tam pro domino rege quam pro se imposo sequitur,' meaning 'who brings the action as well for the king as for himself.' In 1905 the Supreme Court of the United States observed in Marvin v. Trout, 199 U.S. 212, 225, 26 S.Ct. 31, 34, 50 L.Ed. 157 that:
"Statutes providing for actions by a common informer, who himself had no interest whatever in the controversy other than that given by statute, have been in existence * * * in this country ever since the foundation of our government." Bass Anglers Sportsman's Society of America, et al. v. U. S. Hunt Plywood-Champion Papers, Inc., et al., 324 Fl. Supp 302, (S. D. Tx. 1971).

Act, 31 U.S.C. §§3729-33, (FCA) into which the government intervened, after a delay of more than eighteen months. The complaint charged that, among other things, Aging Care Home Health, Inc. (Aging Care), a home heath services provider (HHA), and its principals, Janice Davis and Otis Davis, knowingly and willfully submitted false claims to the Medicare program. The government alleges in its complaint of intervention that the Defendants submitted to the Medicare program false certifications and false or fraudulent claims for services by five physicians that were the product of illegal relationships with those physicians, all in violation of the Stark Act, 42 U.S.C. §1395nn (Stark Act), and the Anti-Kickback Act, 42 U.S.C. §1320a-7b(b) (Anti-Kickback Act). The payments to each of the physicians are said to be between $381 and $3,800 per year.

After suit was filed, Medicare suspended or denied all payments to Aging Care for services provided by physicians who held positions on Aging Care's Professional Advisory Committee. Aging Care filed for bankruptcy protection thereafter. The United States seeks repayment of $427,503.88, together with pre-judgment and post-judgment legal interest.

Summary Judgment Standard

Rule 56 of the Federal Rules of Civil Procedure mandates that a summary judgment:

"shall be rendered forthwith if the pleadings,

depositions, answers to interrogatories, and admissions on file, together with the affidavits, [submitted concerning the motion for summary judgment], if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."

Paragraph (e) of Rule 56 also provides the following:

"When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party."

Local Rule 56.2W also provides that all material facts set forth in a statement of undisputed facts submitted by the moving party will be deemed admitted for purposes of a motion for summary judgment unless the opposing party controverts those facts by filing a short and concise statement of material facts as to which that party contends there exists a genuine issue to be tried.

A party seeking summary judgment always bears the initial burden of informing the court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 106 S.Ct. 2548 at 2552; International Ass'n. of Machinists & Aerospace Workers, Lodge No. 2504 v. Intercontinental Mfg. Co., Inc., 812 F.2d 219, 222 (5th Cir. 1987). However, movant need not negate the elements of the non-movant's case. Little v. Liquid Air Corporation, 37 F.3d 1069, (5th Cir. 1994). Once this burden has been met, the non-moving party must come forward with "specific facts showing that there is a genuine issue for trial." Izen v. Catalina 382 F.3d 566 (5th Cir. 2004); Fed. R. Civ. P. 56(e). All evidence must be considered, but the court does not make credibility determinations. If the movant fails to meet its initial burden, summary judgment should be denied. Little, 37 F.3d at 1075.

However, the non-movant, to avoid summary judgment as to an issue on which it would bear the burden of proof at trial, may not rest on the allegations of its pleadings but must come forward with proper summary judgment evidence sufficient to sustain a verdict in its favor on that issue. Austin v. Will-Burt Company, 361 F. 3d 862, (5th Cir. 2004). This burden is not

satisfied with “some metaphysical doubt as to the material facts,” by “conclusory allegations,” by “unsubstantiated assertions,” or by only a “scintilla” of evidence. Little, id.

The Claims and Defenses

The Stark Act imposes a prohibition on a home health company (HHA), as well as on other medical providers, from billing the Medicare program (or Medicare paying) for services provided to patients who have been referred by physicians with whom the HHA has a financial relationship, like ownership or a contract, that fails to satisfy a statutory or regulatory exception. [42 U.S.C. 1395nn].

In its intervention, the government seeks repayment because of alleged violations of the Stark Act, not only under the False Claims Act (FCA), but also because the payments were, it asserts, made by “mistake” and “unjustly enriched” the HHA and its principals. The government also alleges that the defendants intentionally violated a criminal statute, the Anti-Kickback Act. In this motion, the government seeks summary judgment only with respect to its claims of mistake and unjust enrichment, leaving the allegations pursuant to the FCA and the Anti-Kickback Act, which both require proof of intent, for another day.

The United States contends that the Defendants’ alleged violation of the Stark statute, as it was amended in 1993, “forms the cornerstone” of the claims asserted by it in this Motion.

Defendants assert that the government is attempting "to look back before the regulations were even written and impose liability upon the Defendants for what it now declares to be improper." They point to what has been described as a "bewildering array" of overlapping State and Federal statutes and regulations and suggest, quoting Sir Thomas More's Utopia: "It is unjust to bind the people by a set of laws that are too many to be read and too obscure to be understood."[2] Specifically, defendants argue that during the time period in which almost all the acts alleged occurred the regulations in effect permitted the transactions which are now the subject of the government's claims, as long as the amount of physician compensation did not exceed $25,000. The government responds that while defendants are correct in pointing out that those regulations were in effect during the applicable time period, the amended statute was more restrictive than the regulations and should have been complied with by the defendants who are presumed to know the law.

Statutory and Regulatory Framework

Pursuant to his statutory authority, in 1981 the Secretary promulgated 42 CFR 405.1633 providing rules for requiring physician certification and re-certification which requires that,

[2] A more accurate quotation is [The Utopians] "think it completely unjust to bind men by a set of laws that are too many to be read or too obscure for anyone to understand" Thomas More, Utopia, p. 84-85 (George M. Logan and Robert M. Adams ed., Cambridge University Press, 1989) (1895).

among other things, the home health services were required for certain listed reasons.

In October, 1982, the CFR was amended in order to comply with the Omnibus Reconciliation Act of 1980, [PL 96-499]. That Act provided, for the first time, as to HHAs, that the Secretary had authority to "prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan." The rules and regulations implementing the amended CFR stated that one of the purposes of the Act's changes was "to make it easier for HHAs to meet certification and plan of treatment requirements, while guarding against conflict (sic) of interest in the performance of those functions."

The regulations finally prescribed in 1982, over a year after the deadline imposed by Congress, set forth for the first time the $25,000 limit on which defendants here rely in defense of the government's allegations. That final rule became effective November 26, 1982. [47 FR 47388] It provided that physicians who had a significant financial or contractual interest in the entity could not certify the need for home health services or establish or review plans of treatment. "Significant financial or

contractual interest” was defined as a relationship involving direct or indirect business transactions that amount to $25,000 or 5% of the HHA’s operating expenses for the year, whichever is less. Implementation of the new rules was delayed by the agency for 30 days “because home health agencies and intermediaries and carriers could not apply the prohibitions until we established the criteria and defined the terms.”

In 1986 the Medicare regulations were amended but the provision regarding the $25,000 limit was not changed. [51 FR 23541]. The Agency’s explanation of the rules again stated that the 1982 amendments (contained in the Omnibus Reconciliation Act of 1980) had been delayed because they “could not be implemented without regulations to define the terms used in the law.” Then, in March 1988 the CFR, 42 CFR 1633, was renumbered as 42 CFR 424.22. [53 FR 6629]. Once again, the $25,000 limit was retained unchanged. The regulations were amended again in April 1988 and, as before, the $25,000 limit was not changed. [53 FR 12945].

In 1991 regulations implementing the Omnibus Budget Reconciliation Act of 1987 were made final, effective April 1, 1991. No pertinent change to 42 CFR 424.22 was made.

The first Stark Act was passed in 1989, P.L. 101-239 effective January 1, 1992, known as “Stark I”, was in effect from January 1992 to December 1994 and applied only to relationships between medical laboratories and referring physicians where the

doctors had a financial interest in the laboratory. [42 U.S.C. 1395nn]. The Act provided that the Secretary would promulgate regulations pursuant to the Act's provisions no later than October 1, 1990.

The Medicare statute was amended by what is known as "Stark II" in 1993, effective January 1, 1995.[3] [42 U.S.C. 1395nn]. The new statutory provision provided that, if a physician had a financial relationship with, among others, an HHA, then the doctor could not make a patient referral, and Medicare could not pay the doctor, unless an exception to the rule set forth in the statute applied. Exceptions were set forth for rental of office space or equipment, employment relationships, personal service arrangements, and others. Personal service arrangements, the only exception which could be applicable here, required that the contract 1)be in writing and specify the services to be performed, 2) cover all of the doctor's services, 3) provide for only those services reasonable and necessary for the arrangement, 4) have a term of at least a year, not allow for payment to exceed fair market value of the services to be performed, 5) not involve promotion of a business arrangement that is contrary to law, and, 6) meet "such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse."

[3] Omnibus Budget Reconciliation Act of 1993.

Despite the passage of Stark I in 1989, and Stark II in 1993, the certification regulations in place since 1982 were not "significantly updated" after 1986 until 2001. See 63 FR 1659 @1679; 66 FR 8771. In 1995, certain regulations were promulgated only with regard to physician referrals for clinical laboratory services. [60 FR 41914]

In 1997 a notice of intent was published by the Secretary to reconcile the obviously conflicting provisions of the Regulations with the new Act. [62 FR 59818]. In the proposed rule, published January 9, 1998, [63 FR 1659] it was explained that "we are developing" new provisions under the new Act and the Secretary observed that "it is confusing to have in effect two provisions that address prohibited referrals, each of which includes different criteria, and can lead to different results." The Secretary continued: "We are proposing" to use the new statutory definition of "financial relationship", along with the Secretary's interpretation of the definition in order to develop a new regulation concerning "significant financial or contractual relationship". The explanation continued that "we are proposing" to amend §424.22(d). These proposals, were not, in fact, implemented for another three years, in 2001.[4]

Substantial changes were made to the proposed version of the

[4] A summary of the regulatory history of these regulations is found in 66 FR 856, at 857-859.

rules[5] and the final rule was published January 4th, 2001, with an effective date of February 5, 2001. [66FR 856] However, the effective date was delayed to April 6, 2001. [66 FR 8771] The two new regulations, 42 CFR 411 and 424, regulating 8 pages of the statute, totaled 83 pages. The Secretary's explanation of the two regulations totaled 489 pages. This, 8 years after the new Act (Stark II) was passed.

The Secretary's discussion explained:

> The effect of this statutory scheme is that failure to comply with section 1877 of the Act can have a substantial financial result. For example, if a hospital has a $5,000 consulting contract with a surgeon and the contract does not fit in an exception, every claim submitted by the hospital for Medicare beneficiaries admitted or referred by that surgeon is not payable . . .".

The Secretary observed that the statutory scheme (under Stark II) "obligates us to proceed carefully in determining the scope of activities that are prohibited." He said "[w]e expect that Phase I of this rulemaking will result in savings to the program by providing physicians and entities with 'bright line' rules on how to avoid the prohibited referrals that can result in overutilization of covered services." He added " . . . we believe Phase I of this rulemaking should not require substantial changes in delivery arrangements, although it may affect the referring physician's or group practice's ability to bill for the care."

The Secretary also explained that "[a]fter reviewing the

[5] See 66 FR 856 at 859.

voluminous number of comments we received, we have considered many alternative ways to interpret the statute to accommodate the practical problems that commenters raised, while still fulfilling the intent of the law."

The new rule in 2001 specifically changed the requirements which had to be met in order for a physician with a financial interest in the HHA to receive payment from it. The explanation was that "[w]e are removing the current 5 percent ownership limit and the $25,000 limit on financial or contractual relationships from §424.22(d)." In its place, the regulations now would require that the physician's relationship meet one of the exceptions in other provisions of the new regulations, specifically §§411.355 and 411.357. However, implementation of those new sections was delayed and the new rule provided that in "the interim, the references to §§411.355 and 411.357 will cross-refer to the statutory exceptions set forth in section 1877 of the Act."

Analysis

The United States seeks to recoup the monies it paid Aging Care and its principals in 1999-2003 for violation of the Stark Act (Stark II) under federal common law principles of mistake and unjust enrichment. Citing the regulations put in place in 2001, 66 FR 859, the government asserts that Aging Care had financial relationships with the referring physicians and that the relationships did not fit into one of the "several relatively

specific exceptions." Pointing to the personal services exception, and 42 CFR 411.357(d), put in effect in 2001, the government argues that, because the physicians have admitted in their deposition testimony that they got paid for doing nothing for the most part, the defendants do not meet at least two of the exceptions[6] and summary judgment is appropriate as a matter of law.

Defendants counter that, until the final regulations were promulgated and made final (in 2001), the regulations in effect during the time period regarding which the government complains permitted the actions complained of. Specifically, Aging Care contends that because none of the doctors were compensated as officers or directors of Aging Care, and because none of them received more than $25,000[7] in payments under their respective contractual arrangements with Aging Care, Aging Care was in full compliance with the only regulations in effect at the time. Defendants show that the doctors received between $500 and $7,000 each in all the years complained of, 1999-2001.[8]

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[6] The government claims that the contracts as actually performed were not in writing and they were not for terms of more than one year.

[7] Based on the government's allegations that Aging Care received "millions of dollars in reimbursement" it does not appear that the alternative 5% limitation is applicable to the facts of this case.

[8] Dr. Coats also received remuneration in 2002 of $1,800 and, in 2003, of $1,650 according to defendants.

Although the government's lawyers argue that the provisions of Stark II were easily understood despite the existence of the old regulations which remained in force almost ten years after the Act's passage, the voluminous discussion and comments by the Secretary in the explanations of the new regulations in 2001 belie that argument. The Secretary expressly stated that the regulations were confusing, relied on different criteria and could result in a different result. The Secretary had said that it was necessary to "proceed carefully in determining the scope of activities that are prohibited." It is quite apparent that the Secretary did not think that Stark II could be interpreted or applied without the agency's guidance in the form of regulations. Instead, the agency itself intended to determine the "scope of activities that are prohibited."

The government seeks to turn a blind eye to the extensive regulatory history of these provisions, suggesting that the "United States does not contend in this action, or in its motion, that defendants violated 42 C.F.R. §424.22(d). [footnote omitted] The United States contends that defendants violated the Stark Statute." Nevertheless, the government's brief is unabashedly replete with references to the regulations put in place after the acts of defendants about which it complains.

The illegality or not of defendants' acts cannot be judged by simply reading the Stark Act in a vacuum and without

reference to its regulations, and claiming the defendants were required to know the law. For the extensive regulations under that Act, as amended, had governed the conduct of medical providers like Defendants since 1982. In fact, originally, and until 1989, the only rules proscribing physician-provider financial arrangements were in the Congressionally mandated regulations promulgated pursuant to the Omnibus Reconciliation Act of 1980 [see discussion at page 7].

If the meaning of the Stark Act and how it related to these vast original regulations was intuitive and accomplished by simply reading the Act, it would not have required the agency to take almost ten years to implement the new regulations. It would not have required 83 pages of regulations to explain what the new 8 page Stark Act meant. And it would not have required an additional 489 pages of explanation of the statute and regulations.

It is perhaps most important to observe that the new Act specifically provided for additional exceptions to the prohibition to be promulgated by the Secretary:

> In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse. [PL 103-66]

How could a provider have known that the $25,000 limit, provided for in regulations which had not been revoked, did not, pursuant to the Secretary's intent, constitute an additional

exception which Congress specifically permitted in paragraph (b)(4) of the Act?

Those regulations, which remained in effect governing providers' conduct for almost ten years, cannot now, with the benefit of hindsight and 572 pages of explanation, be ignored. Nor can the Act be interpreted almost ten years later by resort to newer regulations which were not even in effect during that period of time and were only promulgated after the industry put its collective heads together with the Secretary during the comments period.

Further, it is clear that the Secretary never intended nor assumed that the old regulations were not in full effect. First, they were never revoked. Second, discussions by the Secretary were always of "proposed" changes. It was not until 2001 that the Secretary proclaimed that "[w]e <u>are removing</u> the <u>current</u> 5 percent ownership limit and the $25,000 limit on financial or contractual relationships" from the regulations [emphasis added].

Despite numerous references to the new, 2001, regulations, the government argues that the regulations should be ignored, and that the Act, not the regulations, forms the "cornerstone" of its case against Defendants. The regulations in effect during the period of time at issue here cannot be ignored, for they were substantive ones and were a part of the law. Statements made by federal agencies may constitute substantive rules or merely be

general policy statements. Agencies are bound by duly promulgated substantive rules, which have the force of law, while interpretive rules or policy statements do not have binding effect. Dyer v. Secretary, 889 F.2d 682, 685 (6th Cir. 1989). Substantive rules create law, whereas interpretative rules are statements as to what an administrative officer thinks the statute or regulation means.

The regulations on which Defendants rely in defense, in effect for nineteen years (1982-2001), grant rights, impose obligations and produce significant effects on private interests. These regulations did far more than merely explain or clarify the law. See Beverly Health & Rehabilitation v. Thompson, 223 F. Supp. 2d 73 (D. C. Cir. 2002). Indeed, the Secretary had noted, with regard to the regulations under Stark I, that a delay in implementation of the regulations was necessary because they "could not be implemented without regulations to define the terms used in the law." Further evidence that the rules have always been considered substantive comes in the Secretary's cautionary statement in 2001 that the statutory scheme "obligates us to proceed carefully in determining the scope of activities that are prohibited." Additional evidence that the regulations were substantive is found in the fact that the regulations were originally the only source of the rules specifying the

prohibition regarding self-interested physicians.[9]

It is equally clear that the new regulations in 2001 constituted, in the eyes of the Secretary, a change in the existing law. Not only was he "determining the scope of activities that are prohibited", as recited just above, but he acknowledged the fact that the existing regulations remained in effect and created confusion which could lead to results contrary to those under the Act. He further noted that the new rules "should not require substantial changes in delivery arrangements", further proof that the existing regulations still governed conduct up to the effective date of the new regulations.

Perhaps most pertinent to the government's argument that the Defendants here should have complied with Stark II, despite the existence of the conflicting and confusing regulations still on the books, is the fact that following the period for comments the Secretary stated that " . . . we have considered <u>many alternative ways to interpret the statute</u> to accommodate the practical problems that commenters raised, while still fulfilling the intent of the law." [emphasis added] If the 572 pages of regulations and explanation of the regulations does not prove that the Act's provisions were not intuitive or self executing, this statement of the Secretary makes it crystal clear. The Secretary has thus expressly recognized that there exist many

[9] Omnibus Reconciliation Act of 1980.

alternative ways to interpret Stark II, the statute the government now claims the Defendants should have complied with in lieu of the regulations then in full force and effect. It was not until 2001 that the regulations even made reference to the exceptions set forth in the Act. [66 FR 856 at 936]

The extent of government overreaching in this case is astounding and frightening. This enforcement action has apparently bankrupted Defendant, Aging Care. The evidence at this point in the case shows that the Defendants may well have complied with the only substantive regulations then in place and thus with the Stark Act.[10] There exists a genuine issue of material fact. It is therefore not necessary that the court consider whether a federal common law action based on mistake or unjust enrichment is appropriate in this case.

For the foregoing reasons, IT IS RECOMMENDED that the Motion for Partial Summary Judgment by the United States, Doc #149, be DENIED.

OBJECTIONS

Under the provisions of 28 U.S.C. § 636(b)(1)(C) and Fed.R.Civ.P. 72(b), the parties have ten (10) business days from

[10] The statement is qualified because, although Defendants argue in brief that they do not meet the $25,000 threshold, the court does not have sufficient evidence before it to make that determination. Nor have defendants filed a motion for summary judgment on the issue. Neither does the court have adequate evidence before it to sort out the allegations against Dr. Coats who received , according to the brief of defendants, payments after the effective date of the 2001 regulations.

service of this Report and Recommendation to file specific, written objections with the clerk of court. A party may respond to another party's objections within ten (10) days after being served with a copy thereof. A courtesy copy of any objection or response or request for extension of time shall be furnished to the district judge at the time of filing. Timely objections will be considered by the district judge before he makes his final ruling.

FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS CONTAINED IN THIS REPORT WITHIN TEN (10) BUSINESS DAYS FROM THE DATE OF ITS SERVICE SHALL BAR AN AGGRIEVED PARTY, EXCEPT UPON GROUNDS OF PLAIN ERROR, FROM ATTACKING ON APPEAL THE UN-OBJECTED-TO PROPOSED FACTUAL FINDINGS AND LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT JUDGE.

THUS DONE AND SIGNED in chambers, in Alexandria, Louisiana, on this the 30TH DAY OF October, 2006.